K112380
Page 1 of 3

NOV 22 2011

510(k) Summary

Date:	June 9, 2011
Submitter:	Midmark Corporation 675 Heathrow Drive Lincolnshire, IL 60069 USA
Contact Person:	Lisa Bartakovics Director of Quality and Regulatory Affairs (847) 415-9800
Device Name:	ClearVision Digital Sensor System
Predicate Devices:	Schick CDR (K072134) Gendex GXS-700 (K090458), approved under Dexis name
Description of Device:	ClearVision is a digital imaging system for dental radiographic application. The product is to be used for routine dental radiographic examinations such as bitewings, periapicals, etc. Two different sized sensors (size 1 and size 2) are utilized to image different anatomy and for different patient sizes. The CMOS sensor connects directly to a USB connection in a PC without the need for an intermediate electrical interface. ClearVision works with a standard dental intraoral x-ray source without any connection to the x-ray source. ClearVision captures an image automatically upon sensing the production of x-ray and after the x-ray is complete, transfers the image to an imaging software program on the PC. Disposable sheaths are used with each use to prevent cross-contamination between patients.
Intended Use:	ClearVision is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Substantial Equivalence:

Technical Characteristic	ClearVision	Schick CDR	Gendex GXS-700 (Dexis)
Sensor Sizes (mm)	37 x 24 43 x 30	31 x 22 37 x 24 43 x 30	37 x 25 42 x 31
Sensor Technology	CMOS	CMOS	CMOS
Pixel Size (µm)	19.0	40.0	19.5
Scintillator	CsI	CsI	CsI
Interface to PC	USB	USB	USB
Electronic Interface Assembly?	No	Yes	No
Intended Use	ClearVision is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.	The Computed Oral Radiology System is intended for intra-oral examinations and indicated for dental patients. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.	The DEXIS sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.

Tests Conducted:

An imaging performance comparison was done of the ClearVision sensor versus the Schick CDR and Gendex GXS-700 sensors. The details of this testing can be found in Section 18. This testing consisted of using each sensor to image a line pair phantom, an aluminum step wedge, and a tooth phantom. In this testing, the ClearVision sensor was shown to be equivalent to the Gendex GXS-700 in all three tests and superior to the Schick sensor in all three imaging tests.

Significant electrical, mechanical, and imaging tests were performed on the sensors as part of engineering verification. The full details of this testing is found in Section 18. In all cases, the sensor was found to meet the requirements identified earlier in the design phase. Extensive imaging performance testing was done in various configurations of connections of the sensor to a PC workstation (varying lengths of cable and the presence of USB hubs and extenders). The sensor showed itself to be completely reliable in capturing an image and transferring the image to the workstation over an extended life period. Image quality of the sensor was shown to meet requirements and to be consistent over the expected lifetime exposures to radiation. The sensor was put through extensive mechanical testing that tested the durability of the sensor housing and cable. Once again, the sensor met all specified requirements. An external test laboratory confirmed the ClearVision system meets the electrical safety and EMI/EMC provisions of IEC 60601-1 and 60601-1-2. Testing by the sensor supplier by an external laboratory confirmed the sensor met hermetic classification IP67 per IEC 60529.

Conclusion:

The ClearVision sensor system is substantially equivalent to other legally marketed devices in the United States. The ClearVision sensor system is substantially equivalent in technical characteristics and intended use to the CDR sensor marketed by Schick Technologies and the GXS-700 sensor marketed by Gendex Dental Systems (approved under the Dexis name).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NOV 22 2011

Ms. Lisa Bartakovics
Director, Quality and Regulatory Affairs
Progency Dental
Midmark Corporation
675 Heathrow Drive
LINCOLNSHIRE IL 60069

Re: K112380
Trade/Device Name: Progeny ClearVision Digital Sensor System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 18, 2011
Received: October 18, 2011

Dear Ms. Bartakovics:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112380

Device Name: Progeny ClearVision Digital Sensor System

Indications for Use: ClearVision is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Prescription Use X AND/OR Over the Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112380